

Appl. No. 09/939,532
Amdt. Dated June 18, 2003
Reply to Office Action of December 18, 2002

In The Specification:

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On page 5, line 7, replace "palmoate" with --pamoate--.

In The Claims:

Cancel claim 8. Please add new claims 10-12. Please amend claims 1-7 and 9 of this application as indicated below. The following listing of claims replaces all prior versions and listings of claims in this application:

1. (currently amended) A method for ~~producing~~ making peptide salts, which comprises ~~reacting an acid addition salt of a basic starting peptide in the presence of a diluent in a mixed bed ion exchanger, with a mixture of an acid and a basic ion exchanger during the formation of a free basic peptide, and then separating the ion exchanger and then the free basic peptide, with an inorganic or organic acid, and then forming the desired acid addition salt of the peptide, and removing the diluent~~ a composition containing a peptide salt having a pharmaceutically acceptable anion comprising:

contacting a first peptide salt with a diluent to form a diluent solution;

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contacting the diluent solution containing the first peptide salt with a mixed bed ion exchanger, wherein the mixed bed ion exchanger has strongly acidic cations and strong anion exchangers;

separating the mixed bed ion exchanger from the diluent solution;

contacting the diluent solution with an acid having a pharmaceutically acceptable anion, thereby forming an acid addition salt of the peptide having the pharmaceutically acceptable anion;

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adding an adjuvant to the diluent solution; and

separating the diluent from the diluent solution.

2. (currently amended) The method of claim 1, wherein said ~~basic starting peptide is a salt of the first peptide salt~~ is a salt of an LHRH antagonist selected from the group of Cetorelix, Teverelix, Abarelix, Ganirelix, Azaline B, Antide, A-75998, Detirelix, Ramorelix, and RS-68439.

3. (currently amended) The method of claim 1, wherein said acid is ~~embonue~~ embonic acid, stearic acid, or salicylic acid.

4. (currently amended) The method of claim 1, wherein said ~~basic starting peptide is the first peptide salt~~ is Cetorelix acetate, and said acid is embonic acid, and the peptide:acid molar ratio is 2:1.

a' 5. (currently amended) The method of claim 1, wherein said ~~diluent is removed by freeze drying~~ acid addition salt of the peptide is separated from the diluent by freeze drying.

6. (currently amended) A ~~peptide salt when made by the process~~ composition comprising a peptide salt having a pharmaceutically acceptable anion made by the method of claim 1.

7. (currently amended) A pharmaceutical composition ~~which comprises~~ comprising the a peptide salt composition of claim 6, ~~together with~~ and at least one pharmaceutical adjuvant, ~~or in a carrier.~~

8. (cancelled)

9. (currently amended) A ~~process method of treating a mammal with the peptide salt of claim 6, which comprises parenterally administering to the mammal a drug containing said peptide salt as active ingredient~~ treatment for benign prostate hyperplasia, myoma, or

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endometriosis comprising parenterally administering to a patient a composition comprising a peptide salt having a pharmaceutically acceptable anion made by the method of claim 1, wherein a plasma level of greater than 2 ng/mL of an LHRH antagonist is maintained for at least 150 hours after administration.

10. (New) A method of treatment for benign prostate hyperplasia comprising parenterally administering to a patient 60 mg of a composition comprising a peptide salt having a pharmaceutically acceptable anion made by the method of claim 1, wherein a plasma level of greater than 2 ng/mL of cetrorelix is maintained for at least 150 hours after administration.

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11. (New) A method of treatment for myoma comprising parenterally administering to a patient 60 mg of a composition comprising a peptide salt having a pharmaceutically acceptable anion made by the method of claim 1, wherein a plasma level of greater than 2 ng/mL of cetrorelix is maintained for at least 150 hours after administration.

12. (New) A method of treatment for endometriosis comprising parenterally administering to a patient 60 mg of a composition comprising a peptide salt having a pharmaceutically acceptable anion made by the method of claim 1, wherein a plasma level of greater than 2 ng/mL of cetrorelix is maintained for at least 150 hours after administration.
